REMARKS

Claims 21-32 presently appear in this case. Claims 22-24 and 32 have been withdrawn from consideration. Claims 21 and 25-31 have been rejected. The official action of January 25, 2005, has now been carefully studied. Reconsideration and allowance are hereby respectfully urged.

Briefly, the present invention relates to a method for treating a patient having an autoimmune or inflammatory disease in which TNF plays a role, by administering TNF receptor and DHEA in a manner so as to achieve an effective blood level of the combination.

The interview between Examiner Murphy and the undersigned attorney on June 24, 2005, is hereby gratefully acknowledge. In this interview, language was discussed that is supported by the specification and should obviate the indefiniteness and written description questions. Agreement was reached that, if claim 21 was amended as presented herein, it should place the case in condition for allowance.

Claims 21 and 25-31 have been rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement. The examiner states that the specification as originally filed does not provide support for the language "autoimmune and inflammatory diseases against which a TNF receptor is effective."

The language to which the examiner objected, "against which a TNF receptor is effective" has now been deleted from the claims. Instead, claim 21 has been amended to specify that the process is "a method for treating a patient having an autoimmune or inflammatory disease in which tumor necrosis factor (TNF) plays a role." This language is supported by the present specification at page 1, lines 22-25. Accordingly, it is believed that this rejection has now been obviated and that the new language that has been added does not contain any new matter. However, the claim still clarifies what autoimmune or inflammatory disease is being treated, i.e., one in which TNF plays a role. Reconsideration and withdrawal of this rejection are therefore respectfully urged.

Claims 21 and 25-29 have been rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for a method of treating septic shock, does not reasonably provide enablement for a method of treating autoimmune and inflammatory diseases. The examiner states that the claim encompasses the treatment of any and all inflammatory and autoimmune diseases. The examiner states that the limitation "against which a TNF receptor is effective" is new matter and thus the claims are being interpreted to encompass the treatment of any and all autoimmune diseases. This rejection is respectfully traversed.

As discussed in the interview, claim 21 has now been amended so as to clarify that the autoimmune or inflammatory disease being treated is one in which TNF plays a role, as is supported on page 1, lines 22-25, for example, of the specification. The specification specifically refers to the treatment of RA, SLE and MS, and claim 30, referring to these conditions, is not subject to this rejection. Further, the examiner has recognized that the prior art teaches the effectiveness of TNF receptor alone in RA, SLE and the NOD mouse model of diabetes. However, the examiner states that this is not demonstrative of any and all autoimmune and inflammatory conditions.

As pointed out in applicants' amendment of November 9, 2004, and the attachments thereto, at the time of the present invention, it was known that TNF receptor is effective in the treatment of collagen-induced arthritis, autoimmune heart disease, autoimmune uveoretinitis, autoimmune thyroid disease, experimental autoimmune myasthenia gravis, arthritis, pneumonitis, and organ-specific autoimmune diseases. Accordingly, as the claims are specifically directed to the treatment of only those autoimmune and inflammatory disease in which TNF plays a role, and as the prior art is aware that a large number of autoimmune disease can be treated with TNF receptor alone, there is no reason to believe that they cannot also be treated by a combination of TNF receptor and DHEA. This

large number of species within the genus should be sufficient to satisfy the written description requirement for the entire genus. Accordingly, as agreed in the above-mentioned interview, reconsideration and withdrawal of this rejection are respectfully urged.

Claims 21 and 25-31 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite in reciting that the TNF receptor is administered "in combination" with DHEA and then reciting that they are administered "separately." The examiner states that the contradictory steps of the claimed method would not indicate to the skilled artisan the metes and bounds of the claim. This rejection is respectfully traversed.

Claim 21 has now been amended to delete the term "in combination" and to specify that the TNF receptor and the DHEA are administered simultaneously, separately or sequentially "so as to achieve an effective blood level of the combination." This language is supported on page 3, lines 24-27, of the present specification. Thus, it is now clear that, even when administered separately, they must be close enough in time so as to achieve an effective blood level of the combination of ingredients. With this amendment, which is supported by the specification, it is believed that any indefiniteness noted by the examiner has now been overcome. Reconsideration and withdrawal of this

rejection as agreed at the above-mentioned interview are therefore respectfully urged.

As claim 21 has been shown to be allowable hereinabove and claim 21 is generic to the embodiment of the withdrawn claims 22-24 and 32, it is urged that the non-elected species must now be examined and allowed. Thus, consideration and allowance of the previously withdrawn claims is also respectfully urged.

It is submitted that all the claims now present in the case clearly define over the references of record and fully comply with 35 U.S.C. §112. Reconsideration and allowance are therefore earnestly solicited.

Respectfully submitted,

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